

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, *ex*
rel., et al.,

Plaintiffs/Relators,

v.

CENTER FOR DIAGNOSTIC
IMAGING, INC., *et al.,*

Defendants.

Case No. C05-0058RSL

ORDER GRANTING IN PART
AND DENYING IN PART CDI
DEFENDANTS' MOTION TO
DISMISS; GRANTING LEAVE
TO AMEND

I. INTRODUCTION

This matter comes before the Court on a motion filed by two of the three defendants in this *qui tam* action, Center for Diagnostic Imaging, Inc. ("CDI") and Medical Scanning Consultants P.A. (collectively, "defendants"), to dismiss Counts I, II, and III of the plaintiffs/relators' third amended complaint (the "TAC"). A motion to dismiss filed by the third defendant, Onex Corporation, is addressed in a separate order. The Court previously granted CDI's motion to compel arbitration of Count IV, Relator West's employment-related claim.

Defendants contend that the plaintiffs/relators have not alleged their fraud

1 allegations with sufficient particularity or met their pleading requirements pursuant to
2 Federal Rules of Civil Procedure 9(b) and 12(b)(6). At defendants' request, the Court
3 heard oral argument in this matter on March 29, 2011. For the reasons set forth below,
4 defendants' motion is granted in part and denied in part, and the Court grants plaintiffs
5 leave to amend.

6 **II. ANALYSIS**

7 **A. Background Facts.**

8 The following facts are taken from the TAC. Relator Patricia West was formerly
9 employed by CDI as Vice President of Operations and Business Development for the
10 state of Washington. Until her termination in May 2005, she was responsible for the
11 management of operations, marketing, and business development for CDI's Washington
12 diagnostic centers. Relator Alexander Serra is a radiologist and founding partner of
13 Sound Medical Imaging, which provides radiology services to CDI's out-patient
14 imaging centers in the Puget Sound area.

15 CDI is a national radiology and imaging company headquartered in Minnesota that
16 operates 54 diagnostic imaging centers in ten states across the country, including Seattle,
17 Washington. Among other things, its imaging services include magnetic resonance
18 imaging ("MRI"), computed tomography ("CT"), x-ray, and ultrasound procedures.
19 Defendant Medical Scanning Consultants Physicians Association ("MSCPA") is an
20 association of radiologists who perform professional services for CDI patients, including
21 interpreting MRI and CT scans. In nearly all of CDI's diagnostic centers, the reading
22 radiologists belong to MSCPA, with the exception of the radiologists in Washington,
23 Wisconsin, and Duluth, Minnesota. TAC at ¶ 45.

24 According to plaintiffs, CDI "has developed a basic business model for
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1 expansion.” TAC at ¶ 115. The company identifies a radiologist¹ “in a geographic
2 market that it is interested in for the purpose of opening a new diagnostic center.” Id. at ¶
3 115. The targeted radiologist then joins MSCPA or the physicians form their own
4 independent professional associations. As described more fully below, CDI allegedly
5 enters into an arrangement with the physicians group whereby CDI funnels significant
6 sums of money to the group in exchange for the referral of patients.

7 In January 2005, plaintiffs filed suit under seal in this Court. The case remained
8 under seal for several years while the government investigated plaintiffs’ claims. In the
9 interim, plaintiffs have amended their complaint three times, although this motion is the
10 first time the Court has addressed the sufficiency of the complaint. The third amended
11 complaint, which is the operative pleading, contains four claims: (1) Count I alleges that
12 CDI violated the Anti-Kickback Statute (the “AKS”), 42 U.S.C. § 1320a-7b(b) by
13 entering into certain lease and joint venture arrangements with physician groups and
14 funneling money to them in exchange for referrals of government insured patients and by
15 providing free and discounted services to physicians to induce referrals; (2) Count II
16 alleges that CDI violated the Stark Act, 42 U.S.C. § 1395nn by inducing referrals from
17 physicians through improper financing relationships; (3) Count III alleges that CDI
18 violated the False Claims Act, (“FCA”), 31 U.S.C. § 3729-3733 by failing to obtain
19 written orders prior to providing services, offering free and discounted services, and
20 charging more for epidurographies than the billing rules permit; (4) Count IV alleges
21 West’s employment-related claim. Plaintiffs bring the first three claims in a *qui tam*
22 capacity. The government and CDI have entered into a settlement agreement to settle the
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24 ¹ Radiologists are medical doctors who are specially trained to interpret imaging
25 exams to aid a treating physician in patient assessment and diagnosis.

1 claim that CDI up-charged for epidurographies. The government declined to intervene
2 regarding the other claims.

3 **B. Legal Standards.**

4 Defendants have filed a 12(b)(6) motion for failure to state a claim upon which
5 relief can be granted. The complaint should be liberally construed in favor of the plaintiff
6 and its factual allegations taken as true. See, e.g., Oscar v. Univ. Students Co-Operative
7 Ass'n, 965 F.2d 783, 785 (9th Cir. 1992). The Supreme Court has explained that “when
8 allegations in a complaint, however true, could not raise a claim of entitlement to relief,
9 this basic deficiency should be exposed at the point of minimum expenditure of time and
10 money by the parties and the court.” Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 558
11 (2007) (internal citation and quotation omitted). Plaintiffs must show a “plausible
12 entitlement to relief,” which requires more than labels and conclusions. Id. at 555
13 (explaining that a “formulaic recitation of the elements of a cause of action will not do.”);
14 Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (“To survive a motion to dismiss, a
15 complaint must contain sufficient factual matter, accepted as true, to state a claim for
16 relief that is plausible on its face.”).

17 Conclusory allegations of fraud are insufficient. Bly-Magee v. California, 236
18 F.3d 1014, 1019 (9th Cir. 2001). Instead, to comply with Rule 9(b), allegations of fraud
19 must state the who, what, when, where and how of misconduct. Vess v. Ciba-Geigly
20 Corp., 317 F.3d 1097, 1106 (9th Cir. 2003). That standard also applies in FCA cases.
21 See, e.g., Bly-Magee, 236 F.3d at 1019 (citing Wang v. FMC Corp., 975 F.2d 1412, 1419
22 (9th Cir. 1992) (explaining that insiders should have knowledge of the alleged
23 wrongdoing and be able to comply with Rule 9(b)); Frazier v. Iasis Healthcare Corp.,
24 2010 U.S. App. LEXIS 16894 at *2-3 (9th Cir. Aug. 12, 2010). The allegations “must be
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specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong.” Bly-Magee, 236 F.3d at 1019. A FCA plaintiff “is not required to plead representative examples of false claims submitted to the Government to support every allegation, but he must plead with sufficient particularity to lead to a strong inference that false claims were actually submitted.” Frazier, 2010 U.S. App. LEXIS 16894 at *2-3 (citing Ebeid v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010)).

C. False Claims Act and Anti-Kickback Statute Claims.

The federal False Claims Act, 31 U.S.C. § 3729, provides, in relevant part:

(a) Liability for certain acts.

(1) In general. Subject to paragraph (2), any person who--

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

....

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

Plaintiffs contend that defendants violated the FCA by up-coding, by submitting claims for procedures that were not medically necessary because they were not supported by a written order from a physician, and by offering free and discounted services as inducements for referrals.

The AKS makes it a crime to knowingly and willfully offer, pay, solicit or receive any remuneration to induce a person: (1) to refer an individual to a person for the

furnishing of any item or service covered under a federal health care program; or (2) to purchase, lease, order, arrange for or recommend any good, facility, service, or item covered under a federal health care program. 42 U.S.C. § 1320a-7b(b)(1) & (2). When analyzing alleged violations of the Anti-Kickback statute, a key distinction is that the law “does not criminalize referrals for services paid for by Medicare or Medicaid – it criminalizes knowing and willful acceptance of remuneration in return for such referrals.” Klaczak v. Consol. Med. Transp., 458 F. Supp.2d 622, 678 (N.D. Ill. 2006). The AKS covers arrangements if even one purpose of remuneration was to obtain referrals or induce further referrals of Medicare patients. United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989). Plaintiffs contend that defendants violated the AKS by funneling millions of dollars to physicians in exchange for referring government insured patients to CDI and by providing free and/or low cost services as inducements for referrals.

1. Arrangements with Physicians Groups.

a. The Nature of the Arrangements.

Plaintiffs contend that CDI violated the False Claims Act and federal and state² anti-kickback statutes by entering into certain arrangements with referring physicians groups to direct millions of dollars to those groups to induce them to refer patients to CDI. TAC at ¶ 358. The TAC alleges that beginning in 2001, CDI entered into lease and joint venture arrangements with physicians and physician practices to “funnel illegal kickbacks to physicians groups across the country to induce Medicare and Medicaid referrals.” Id. at ¶¶ 185, 187. Plaintiffs contend that CDI has used three types of lease

² Plaintiffs contend that defendants violated the anti-kickback statutes of Washington, Indiana, Wisconsin, Florida, Illinois, Kansas, and Ohio. The parties’ memoranda do not separately address the state law anti-kickback laws. As the parties did, the Court will analyze those claims consistently with the federal claim.

1 and joint venture arrangements: (1) facility leasing (or “Per Click”) arrangements, (2) “in-
2 office” scanner arrangements, and (3) equipment joint venture arrangements. Id. at ¶ 188.
3 Relator West claims that a CDI Vice President expressly instructed CDI executives on
4 how to aggressively market the lease and joint venture arrangements to physician groups.
5 Under all three arrangements, physicians groups were incentivized to refer patients to
6 CDI; the more referrals they made, the greater the financial rewards. Id. at ¶¶ 235-36.

7 Under the facility leasing arrangement, CDI establishes an imaging center
8 geographically near a physicians group and provides all of the capital, office space,
9 equipment and personnel, and provides all diagnostic imaging services, including using a
10 radiologist to interpret the results. The physicians group refers patients to the CDI
11 imaging center and bills insurers for the technical component of the services even though
12 it did not perform the diagnostic services or incur the costs of operating the center. TAC
13 at ¶ 201. In turn, the physicians group pays CDI a “leasing” fee on a per service or per-
14 click fee basis. “For each technical component fee that the physicians group collects, it
15 pays a portion of that fee back to CDI.” Id. at ¶ 202. The physicians group retains the
16 difference between the reimbursement it received and the “per click” fee it pays CDI. Id.
17 at ¶ 203, Ex. A. Although the per click fee is not paid for government insured patients,
18 CDI required that physicians groups refer their Medicare and Medicaid patients to CDI in
19 order to be eligible for the facility leasing arrangement. Id. at ¶ 205. CDI entered into
20 these arrangements with small and medium sized physicians groups in Kansas,
21 Minnesota, Wisconsin, Illinois, Indiana, Missouri, and Florida. Id. at ¶ 196.

22 Plaintiffs also contend that CDI used a variant of the facility leasing arrangement,
23 what they refer to as the “In-Office Scanner” arrangements, to induce additional referrals
24 from large physicians groups in Minnesota, Wisconsin, Illinois, Kansas, Indiana,
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1 Missouri, and Florida. TAC at ¶ 211. Under the arrangement, CDI forms an LLC
2 partnership with a large physicians group, provides a scanner in their offices, provides
3 office equipment and supplies, personnel, and site build-out, and offers to “loan” the
4 physicians group all, or substantially all, of the physicians group’s portion of the capital
5 investment. CDI then recoups the loan by deducting periodic payments on the amounts
6 from the ownership dividends paid to the physicians group as a co-owner of the LLC. Id.
7 at ¶¶ 214-216. The physicians group refers its Medicare and privately insured patients to
8 the center, CDI performs the imaging services, and submits claims for reimbursement.
9 When the reimbursement is received, CDI retains a portion for its imaging services and
10 sends the remainder to the LLC, which in turn pays its profits as dividends to the
11 physicians group and CDI. Id. at ¶ 220. Under that arrangement, the physician group
12 “earns substantial money for doing nothing more than referring its Medicare and non-
13 Medicare patients” to the CDI center. Id. at ¶ 221, Ex. B.

14 Plaintiffs also contend that CDI entered into illegal Equipment Joint Venture
15 Arrangements (“EJVA”) with physicians groups in Minnesota, Wisconsin, Illinois,
16 Kansas, Indiana, Missouri, and Florida. TAC at ¶ 225. Under that model, CDI and the
17 physicians group establish and co-own a joint venture that would purchase and maintain
18 diagnostic equipment with what CDI described in a presentation as a “minimal capital
19 outlay” from the physicians group. Id. at ¶ 227. As with the in-office scanner
20 arrangement, CDI offers to “loan” the physicians group all, or substantially all, of the
21 physicians group’s portion of the capital investment, then recoups the loan by deducting
22 periodic payments on the amounts from the ownership dividends paid to the physicians
23 group. CDI executes a rental agreement with the joint venture for use of the diagnostic
24 equipment, paying per scan (or “per click”) for use of the equipment. Under the

1 arrangement, “the ‘per-click’ fee flows in the opposite direction of the per-click fee in the
2 facility lease arrangement, *i.e.*, CDI pays the per-click fee to the EJVA, which is a thinly-
3 veiled per-click referral fee.” *Id.* at ¶ 228. The physicians group refers its Medicare and
4 non-Medicare patients to CDI, which performs diagnostic imaging and makes claims for
5 reimbursement to the government or to the applicable private insurance. CDI pays the
6 joint venture the per-click fee for each privately insured scan it performs, then the fee is
7 divided among the owners of the joint venture: CDI and the physicians group. As a result
8 of the arrangement, the physicians group that referred the patients earns a fee for the
9 referral. Although plaintiffs acknowledge that the per-click fee is not paid for the referral
10 of government-insured patients, they contend that the referral fee for privately insured
11 patients is deliberately lucrative enough to compensate physicians groups for all referrals.
12 Absent the referrals of both types of patients, the EJVA model would not work. *Id.* at
13 ¶ 231. Plaintiffs contend that CDI provided Relator West received a detailed spreadsheet
14 that included CDI’s estimate that its proposed EJVA “CDI Seattle Everett” would result in
15 net income of nearly \$100,000 to the physician group in the EJVA’s first year. *Id.* at
16 ¶ 232.

17 **b. Allegations Against CDI.**

18 Plaintiffs concede that the agreements, on their face, exclude government insured
19 patients. TAC at ¶¶ 185, 204, 231. Despite those statements, plaintiffs contend that CDI
20 violated the law by requiring physicians to refer Medicare patients. *Id.* at ¶¶ 205, 231.
21 Plaintiffs describe the arrangements in detail.³ In addition, plaintiffs allege that CDI’s
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23 ³ Plaintiffs also allege that CDI’s 2003 marketing presentation to Orthopedics
24 International demonstrated that Medicare referrals were sent to CDI under the
25 arrangements. TAC ¶ 206. Defendants have filed a copy of that presentation and it does
26 not support plaintiffs’ position.

1 former Chief Development Officer informed Relator West in the Spring of 2004 that
2 physicians were required to agree to refer all of their Medicare patients to CDI as a
3 condition of the facility leasing arrangement. Id. at ¶¶ 207-08. Plaintiffs also allege that
4 CDI provided Relator West “with Excel spreadsheets containing financial calculators
5 utilized by CDI to demonstrate to physicians groups the amount of kickbacks they would
6 receive if they participated in one of CDI’s three lease and joint venture arrangements.”
7 Id. at ¶ 192. Plaintiffs contend that CDI used those calculators to induce physicians to
8 enter into the arrangements. Although those allegations are terse, they are sufficient to
9 state a claim that CDI designed and used the arrangements to induce referrals from
10 physicians groups in violation of the AKS.

11 CDI argues that plaintiffs have failed to offer sufficient details about the
12 arrangements, including specifically identifying the participating physician groups, their
13 location, the dates or amounts billed, the identity of the patients involved, the dates the
14 contracts were entered into, or the dates of the allegedly improper actions. Although
15 plaintiffs do not identify the participating physicians groups by name, the TAC essentially
16 alleges that all of the groups that participated in the lease arrangements were offered
17 and/or received kickbacks. That argument, though broad and subject to Rule 11,
18 sufficiently identifies the participants to allow CDI to respond. CDI argues that plaintiffs
19 have failed to plead the specifics of the agreements, but the “courts have not held that
20 proof of an agreement to refer program-related business is a prerequisite to establishing a
21 violation” of the AKS. Hanlester Network v. Shalala, 51 F.3d 1390, 1396 (9th Cir. 1995).
22 In *Hanlester Network*, the court found that the AKS was violated when a Hanlester
23 representative made representations to limited partners to induce referrals, including
24 telling them that they would be pressured to leave the partnership if they did not refer
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1 business. Id. at 1399. Plaintiffs' allegations in this case are similar.

2 Because of the nature of plaintiffs' claims, this case is similar to *Singh v. Bradford*
3 *Reg'l Med. Ctr.*, 2006 U.S. Dist. LEXIS 65268 (W.D. Pa. Sept. 13. 2006), in which the
4 court rejected defendant's argument that plaintiff had to plead patient-specific false claims
5 in alleging Stark Act and AKS violations. The court noted that it could not see "how
6 requiring Relators to provide a single claim example would put Defendants in a better
7 position to answer and defend against the claims where . . . falsity of the instant claims
8 does not turn on anything unique to any individual claim or that would be revealed from
9 an examination of any claim [because] the claims are false because of the improper
10 financial arrangements," which "does not rely on any specific claim." Id. at *19-20.
11 Similarly, in this case, plaintiffs' claims hinge on the allegedly improper financial
12 relationships, which have been sufficiently alleged, combined with the statement of a high
13 level CDI representative about the purpose of the arrangements. Furthermore, the AKS
14 prohibits willfully *offering* remuneration to induce the referral of program-related
15 business, so proof of payment is not required. Therefore, for purposes of this motion,
16 plaintiffs have sufficiently alleged the improper scheme and that CDI offered remuneration
17 in exchange for the referral of program-related business.

18 Plaintiffs also allege that CDI acted knowingly. CDI is aware of the law, cognizant
19 of its own arrangements detailed above, and knew that paying physician groups to refer
20 their government insured patients was unlawful. TAC at ¶ 235. Plaintiffs contend that
21 CDI continued to push for and use their illegal arrangements, even though the Office of
22 the Inspector General ("OIG") issued a Special Advisory Bulletin, a Special Fraud Alert,
23 and an Advisory Opinion warning about the potential illegality of similar joint venture
24 agreements. Id. at ¶¶ 237-244. Plaintiffs's allegations regarding wilfullness are also

1 supported by the alleged statement to Relator West from CDI's former Chief Development
2 Officer and the documents reflecting financial calculations CDI used to demonstrate the
3 amount of potential kickbacks to physicians. *Id.* at ¶¶ 192, 207-08. Accordingly, the
4 allegations regarding wilfulness are sufficient.

5 **c. Allegations Against MSCPA.**

6 Because most of the allegations in the TAC refer to "defendants" collectively even
7 though some of the allegations make little sense against MSCPA, it is unclear exactly what
8 claims are being asserted against MSCPA. It appears that the TAC alleges that defendant
9 MSCPA is liable for FCA violations under the lease arrangements because its physicians
10 were performing and receiving payment for the diagnostic testing services that were
11 illegally referred to CDI. TAC at ¶¶ 46-50. The allegations against MSCPA are scant.
12 Plaintiffs contend that MSCPA "routinely assigns to CDI the right to submit claims" to the
13 government for payment, and, "upon information and belief, MSCPA is a "knowing and
14 voluntary participant in CDI's scheme to submit false claims toe the United States." *Id.* at
15 ¶¶ 47, 50. Plaintiffs do not identify a single false claim submitted by MSCPA. Although
16 that deficiency is not fatal to the claim, plaintiffs also fail to allege any other details,
17 including where the claims were submitted, when, by whom, or any facts to support
18 plaintiffs' "belief" that MSCPA was a knowing participant in the scheme to submit false
19 claims. A plaintiff relying on "information and belief" must state the factual basis for the
20 belief, but plaintiffs have failed to do so. *See, e.g., Neubronner v. Milken*, 6 F.3d 666, 672
21 (9th Cir. 1993). Accordingly, defendants' claims against MSCPA are dismissed as
22 insufficient.

23 **2. Add-on Tests, Free or Discounted Services as Inducements.**

24 Plaintiffs also contend that CDI provided remuneration in the form of free or
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1 discounted services to induce referrals in violation of federal and state anti-kickback laws
2 and the FCA. Plaintiffs allege that CDI, based on its own internal protocols, automatically
3 added free or discounted MRAs (Magnetic Resonance Angiography) without a written
4 order from physicians to MRI exams ordered. TAC at ¶ 292. Relator West contends that
5 she raised the issue with CDI Chief Accounting Officer Don Jacobsen. Jacobsen allegedly
6 subsequently stated that performing the add-on procedures was “potentially medically
7 unnecessary” and outside the scope of the work ordered. *Id.* at ¶¶ 297-98. The alleged
8 failure to obtain proper written orders may support a FCA claim as discussed below but
9 plaintiffs have not shown how it supports the alleged AKS violation. Rather, the AKS
10 claim turns on whether CDI provided the free and discounted services as inducements for
11 referral of government insured patients.

12 **a. The Alleged Nationwide Scheme.**

13 Plaintiffs contend that the free or reduced fee “add-on” services were improper
14 inducements for two reasons: (1) the conduct encourages the over-utilization of MRI tests
15 because “it is likely” that physicians “may” order more MRIs than are medically necessary
16 in order to obtain the free MRAs, and (2) “since the free MRA test results are given to the
17 ‘referring doctor’ who is treating the patient, the doctor is receiving a benefit from the free
18 services and indirect remuneration in exchange for sending his MRI and other diagnostic
19 imaging tests to CDI.” TAC at ¶ 308. The first theory is too speculative to state a claim.
20 Furthermore, both theories are undermined by the fact that plaintiffs do not allege that the
21 referring physicians were even aware that CDI was not charging for the MRAs. In fact,
22 the TAC alleges that CDI bills third party payors, not the physicians. *Id.* at ¶¶ 200, 220.
23 Without such knowledge, there is no inducement for referrals. Therefore, the allegations
24 are insufficient to state a claim.

1 Even if the allegations satisfied Rule 12(b)(6), they are insufficient under Rule 9(b).
2 Defendants contend that plaintiffs' allegations are too vague and fail to include specifics.
3 Plaintiffs allege that during a meeting in June 2004, a CDI physician at an unnamed
4 location informed Relator West and his staff that he performed free MRAs on his MRI
5 patients "as an 'added' service for his referring physicians, to get more business." Id. at
6 ¶ 306. That statement is insufficient because it fails to include the physician's location, to
7 state that he performed the free tests to obtain government insured referrals, or to identify
8 any other physicians who referred to CDI as a result or the details of any such referrals.
9 Nor can plaintiffs extrapolate a broader scheme from that lone statement. Plaintiffs, as self
10 described "high level insiders," should be able to provide specifics to support their claims.
11 Plaintiffs' Opposition at p. 1; Bly-Magee, 236 F.3d at 1019; Lee v. SmithKline Beecham,
12 Inc., 245 F.3d 1048, 1052 (9th Cir. 2001). Therefore, plaintiffs have failed to sufficiently
13 allege their claim of a nationwide scheme to induce referrals by providing free or
14 discounted services.

15 **b. Free Services at Mountlake Terrace Facility.**

16 Plaintiffs allege that CDI's internal audit at its Mountlake Terrace Facility from
17 2003-2004 revealed a substantial percentage of MRAs performed for free or for a reduced
18 charge. TAC at ¶¶ 304-05. Medicare beneficiaries were not provided the discounted rate,
19 which might mean that the safe harbor is inapplicable. Id. at ¶ 305; 42 C.F.R.
20 § 1001.952(h)(3)(iii). Plaintiffs contend that Exhibit E to the TAC is a list of 26 patients
21 who received free MRAs at CDI's Mountlake Terrace facility. Although patient names
22 have been redacted, the list includes the date of service, medical record number, and
23 referring physician. However, as with the allegations about a nationwide scheme,
24 plaintiffs fail to allege that the physicians who referred to the Mountlake Terrace facility

1 knew that they were receiving free services.

2 The TAC also alleges that CDI physicians at the Mountlake Terrace facility
3 “performed two x-rays on patients as an ‘added service’ to referring physicians from
4 Sound Urological for no charge” to induce referrals of governmental insured and privately
5 insured patients. TAC at ¶ 311. Plaintiffs allege that CDI specifically marketed the free
6 services to Sound Urological, which then consequently referred patients to CDI. Although
7 those allegations come closer to satisfying plaintiffs’ pleading requirements than their
8 other allegations, they still fail to allege the “who” (patient names) and the “when” (when
9 the free services were allegedly offered and/or performed. Without that information, CDI
10 will be unable to defendant against the claim. Therefore, plaintiffs’ allegations fail to
11 satisfy Rule 9(b).⁴

12 **c. Discounted Services.**

13 Although plaintiffs contend that defendants offered discounts to induce referrals,
14 they have failed to allege that the discounted services were offered for less than fair
15 market value, which is “the gauge of value when assessing the remuneration element of
16 the offense.” Klaczak, 458 F. Supp. 2d 622, 678-79 (N.D. Ill. 2006). Nor have they
17 alleged that the discounted prices were not commercially reasonable. See Department of
18 Health & Human Services, OIG Advisory Opinions 99-2 (Feb. 26, 1999). Without
19 alleging the fair market value of those services, plaintiffs have failed to plausibly allege
20 that the “discounted” services constituted remuneration.

21 In addition to failing to sufficiently allege an AKS violation in connection with the
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23 ⁴ The TAC alleges that in addition to the two free x-rays, CDI offered other
24 discounts to Sound Urological. TAC at ¶ 311. Without providing any specifics,
25 however, that allegations fails to state a claim or to meet the requirements of Rule 9(b).

1 discounted services, plaintiffs' allegations fail to allege a violation of the False Claims
2 Act. The FCA allegations in that regard are untethered to any specific statutory or
3 regulatory provision. Although the TAC alleges that the discounts violated Medicare's
4 "most favored nation" pricing, plaintiffs appear to have abandoned that argument and their
5 response makes no reference to it. In fact, if the MRAs were provided for free, then by
6 definition CDI did not bill for them and no false claims were submitted. Therefore, the
7 Court dismisses plaintiffs' FCA claim based on the provision of free and/or discounted
8 procedures.

9 **3. Failure to Obtain Written Orders.**

10 Plaintiffs contend that CDI intentionally submitted thousands of false claims to
11 Medicare for radiological exams without obtaining a written order from the treating
12 physician in violation of the False Claims Act and the Medicare regulations. TAC at ¶¶
13 261, 265; *id.* at ¶271 (citing 42 C.F.R. § 410.33(d)). The crux of plaintiffs' claims is that
14 all procedures performed in an Independent Diagnostic Testing Facility ("IDTF") must be
15 specifically ordered in writing by the physician treating the beneficiary *before* the
16 procedure is performed. TAC at ¶ 262; *see also* TAC at ¶ 275 (stating that Relator West
17 discovered the absence "of an appropriate written order on the date of service" in some
18 federal beneficiary patient files audited at the Mountlake Terrace Facility) (emphasis in
19 TAC); *id.* at ¶¶ 276-77 (same regarding Minnesota facilities). Otherwise, plaintiffs claim,
20 the IDTF submits a false claim when it seeks reimbursement.

21 As an initial problem, plaintiffs conceded during oral argument that West reviewed
22 physical files only at the Mountlake Terrace facility. For the other CDI facilities, the
23 allegations are based on West's review of whether orders were scanned into electronic
24 files. TAC at ¶¶ 285-91. However, the absence of scanned orders does not necessarily
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1 mean that the files lacked appropriate documentation.

2 Defendants also contend that they were not required to obtain a written order prior
3 to performing any procedures. Medicare and other federal health care programs require as
4 a condition of coverage that services rendered must be reasonable and medically
5 necessary. 42 U.S.C. § 1395y(a)(1)(A). Medicare also requires that all diagnostic tests
6 “must be ordered by the physician who furnishes a consultation or treats a beneficiary for
7 a specific medical problem” 42 C.F.R. § 410.32(a). “Tests not ordered by the
8 physician who is treating the beneficiary are not reasonable and necessary.” Id. 42 C.F.R.
9 § 410.33(d) states that all procedures performed by an IDTF “must be specifically ordered
10 in writing by the physician who is treating the beneficiary.” However, none of the sources
11 plaintiffs cite states that an IDTF’s subsequent claim for reimbursement is false if the
12 IDTF does not obtain a written order prior to performing the service. In fact, the case on
13 which plaintiffs rely suggests otherwise. In *KGV Easy Leasing Corp. v. Leavitt*, 2011 WL
14 491010 (9th Cir. Feb. 14, 2011), the Ninth Circuit considered the written order
15 requirement. The court noted that 42 C.F.R. § 410.33(d) “mandates both that (1) the
16 beneficiary’s treating physician order the tests; and (2) the results are used ‘in the
17 management of the beneficiary’s specific medical problem.’” Id. at * 1. Instead of stating
18 that a prior written order was required, the court noted that KGV “never presented
19 evidence that supplemented the information contained on its [unsigned] order forms or
20 otherwise established medical necessity, such as medical records or signed declarations
21 from the physicians named on the forms.” Id. at * 1. That discussion demonstrates that an
22 IDTF can fulfill its obligations with documentation created after the procedure has been
23 performed as long as medical necessity is supported when the claim is submitted for
24 reimbursement. Therefore, plaintiffs’ claim based on the failure to obtain a prior written

1 order fails.

2 Even if the regulation requires a prior written order, as defendants note,
3 “[v]iolations of law, rules or regulations alone do not create a cause of action” under the
4 FCA. U.S. ex. rel. Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996). Rather, “some
5 request for payment containing falsities made with scienter (i.e., with knowledge of the
6 falsity and with intent to deceive) must exist.” Id. at 1265. The TAC relies on the absence
7 of written orders prior to performing the procedures without alleging that CDI failed to
8 obtain appropriate documentation prior to submitting claims. Accordingly, the TAC fails
9 to state a claim under Rule 12(b)(6).

10 **D. The Stark Act.**

11 The Stark Act, also referred to as the Physician Self-Referral Law, prohibits two
12 things if a physician or member of his or her immediate family has a direct or indirect
13 “financial arrangement with an entity:” (1) the physician “may not make a referral to the
14 entity of certain designated health services” covered by the Medicare program; and (2) the
15 entity “may not present or cause to be presented” a claim to Medicare for any such
16 services following any such referral. 42 U.S.C. § 1385nn(a)(1)(A) & (B).

17 Plaintiffs contend that CDI’s facility lease arrangements violate the Stark Act
18 because CDI had financial relationships with the physicians groups that participated in
19 CDI’s facility leasing arrangements, CDI was an “entity” for purposes of the Stark Act
20 because it performed and billed the diagnostic imaging services for the government
21 insured patients who were referred by the physicians participating in CDI’s lease
22 arrangements, the referrals were for “Designated Health Services” as defined by Stark Act
23 regulations, and CDI presented claims to Medicare for designated health services referred
24 from physician groups involved in CDI’s lease arrangements. TAC at ¶¶ 251, 366-368;

1 see also 66 Fed. Reg. 856 (defining “entity” during the relevant time for purposes of the
2 referral prohibition “as the business organization, or other association that actually
3 furnishes, or provides for the furnishing of, a service to a Medicare or Medicaid patient
4 and bills for that service”). Plaintiffs confirmed during oral argument that their Stark Act
5 claims relates only to the facility lease arrangements.

6 Defendants argue that CDI was not an “entity” because the physicians groups billed
7 and received payments from Medicare. In fact, the TAC explicitly alleges that regarding
8 the facility leasing agreements, the physicians groups billed and received reimbursements.
9 (*id.* at ¶¶ 200-203). Accordingly, plaintiffs have failed to allege that CDI was an “entity”
10 for purposes of the facility leasing arrangements, and their Stark Act claim is dismissed.

11 **E. Leave to Amend.**

12 As set forth above, the Court dismisses plaintiffs’ (1) AKS and FCA claims based
13 on defendants’ alleged provision of free and discounted services to induce referrals, (2)
14 plaintiffs’ claim against MSCPA, (3) plaintiffs’ FCA claim based on the failure to obtain
15 prior written orders, and (4) plaintiffs’ Stark Act claim. In their response to the motion to
16 dismiss, plaintiffs requested leave to amend if the Court is inclined to dismiss any of their
17 claims. Leave to amend should be granted “when justice so requires.” See, e.g., Owens v.
18 Kaiser Found. Health Plan, 244 F.3d 708, 712 (9th Cir. 2001). Although this is plaintiffs’
19 third amended complaint, this motion is the first time the sufficiency of the complaint has
20 been adjudicated. Defendants will not suffer prejudice if leave to amend is granted.
21 Plaintiffs will be granted leave to amend to augment their allegations.

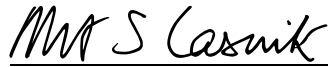
22 However, plaintiffs will not be granted leave to amend their allegations that
23 defendants violated the Stark Act by engaging in the facility leasing arrangements. The
24 TAC specifically alleges that under those arrangement, the physicians groups bill the
25

1 government and receive reimbursement. Therefore, defendants are not an “entity” for
2 purposes of the Stark Act and that claim fails as a matter of law.

3 **III. CONCLUSION**

4 Accordingly, CDI’s motion to dismiss (Dkt. # 85) is GRANTED IN PART AND
5 DENIED IN PART. The motion is denied with respect to plaintiffs’ claims that CDI
6 violated the AKS and FCA through the leasing arrangements. The Court dismisses
7 plaintiffs’ (1) AKS and FCA claims based on defendants’ alleged provision of free and
8 discounted services to induce referrals, (2) plaintiffs’ claim against MSCPA, (3) plaintiffs’
9 FCA claim based on the failure to obtain prior written orders, and (4) plaintiffs’ Stark Act
10 claim. Plaintiffs are granted leave to amend the dismissed claims except for the claim that
11 defendants violated the Stark Act through their facility leasing arrangements; that claim is
12 dismissed without leave to amend.

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14 DATED this 4th day of April, 2011.

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18 Robert S. Lasnik
19 United States District Judge
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